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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,569	12/22/2003	Arnold L. Demain	P-8472-US	7974

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EXAMINER	
MARX, IRENE	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
11/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,569	DEMAIN ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/28/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 25-34* is/are pending in the application.

4a) Of the above claim(s) *1-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22 and 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/28/07 has been entered.

Claims 21-22 and 25-34 are being considered on the merits.

Claims 1-20 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castell (I) or (II) taken with Braun *et al.* (FEMS Microbiology Letters vol. 184 (2000), pages 29-33) and Rolfe *et al.* (Infection and Immunity, 1979, vol. 25, pages 191-201).

Castell (I) and (II) each discloses a culture medium substantially free of animal products and containing *C. difficile,* comprising a compound derived from a vegetable and an iron source. See, e.g., Table 1, respectively, Table 2, page 466.

The references differ from the claimed invention in that a grass extract rather than a soy hydrolyzate is used in the medium and in that yeast extract and/or thioglycolate are not disclosed.

However, Braun *et al.* disclose a culture medium containing *C. difficile,* comprising yeast extract and a compound derived from a vegetable, such as trypticase soy broth, which comprises a soy peptone See, e.g., page 31, col. 2, paragraph 1. In addition Rolfe *et al.* discloses the cultivation of *C. difficile* on thioglycolate medium which contains sodium thioglycolate . See,

e.g., Table 1. The thioglycolate medium comprises yeast extract and enzymatic digests of proteins, which may be soy and/or casein. Even though trypticase soy broth and thioglycolate medium may comprise a casein hydrolyzate, for example, these product of animal origin are substantially degraded to amino acids and peptides prior to addition to the culture medium. It is submitted that their peptide and amino acid composition is not clearly distinguishable from similar hydrolyzates of vegetable origin, in the absence of evidence to the contrary. In any event, each of the Braun *et al.* and Rolfe *et al.* demonstrate that yeast extract is a well-known additive for culture media of *C. difficile* and Rolfe *et al.* additionally demonstrates that sodium thioglycolate is know to be used in media for *C. difficile.*

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the culture media of Castell (I) and (II) by adding a soy hydrolyzate as taught by Braun *et al.*, and yeast extract as taught by Braun *et al.* and Rolfe *et al.* as additional sources of nutrients as well as adding sodium thioglycolate as disclosed by Rolfe *et al.* for the expected benefit of providing a suitable nutrient medium for the anaerobic cultivation of *C. difficile* obtained from clinical samples, for example.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The arguments directed to the differences in composition between vegetable peptone and casein hydrolyzate are noted. However, inasmuch as the claimed composition does not require specific amounts of vegetable peptone or hydrolyzed soy product or soy peptone, any unexpected results alleged are not commensurate in scope with the claims. It is noted in this regard that Table 6 compares various compositions for Toxin A production. An unidentified "peptone" is compared with specific products, which are not particularly identified as to content. It is noted that there is no clear indication whether the same strain was cultured and whether the comparison is side-by-side. In any event, it is noted that Toxin A production is higher for some and lower for others than "peptone". The claims are not directed to a specific culture medium shown to be particularly effective for the production of toxin A or to a process of production of toxin A, but

rather the claims are broadly directed to a culture medium containing various unidentified ingredients in unidentified amounts, such as yeast extract, any compound derived from a vegetable, a soy product, vegetable peptone, any iron source, etc. in various combinations and comprising *C. difficile.* This is not the invention touted.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651